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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Craig Glascott
Serial No. : 10/043,550 Art Unit: 3732
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For : POLYAXIAL SCREW WITH IMPROVED LOCKING

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APPEAL BRIEF

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I. REAL PARTY IN INTEREST

The present case is assigned to DePuy AcroMed, Inc. by way of an assignment recorded at Reel 012765, Frame 0069 in the United States Patent and Trademark Office. DePuy AcroMed, Inc. has since changed its name to DePuy Spine, Inc. and is a subsidiary under the control of Johnson & Johnson, a New Jersey corporation.

II. RELATED CASES

Applicant is unaware of any related appeals or interferences.

III. STATUS OF THE CLAIMS

Presently, claims 1 to 8 are pending in the application. Claims 1 to 3, 5 and 6 stand rejected under 35 U.S.C. § 102(b) over the Tatar U.S. Patent No. 5,910,142. Claims 1 to 3 and 5 to 7 stand rejected under 35 U.S.C. § 102(b) over the Biedermann et al. U.S. Patent No. 5,443,467. Claim 4 stands rejected under 35 U.S.C. § 103(a) over Tatar in view of the Sherman et al. U.S. Patent No. 5,885,286. Claim 8 stands rejected under 35 U.S.C. § 103(a) over Biedermann et al.

IV. STATUS OF AMENDMENTS

No amendments have been submitted since the mailing of the Final Office Action.

IV. SUMMARY OF THE INVENTION

The present invention provides a pedicle screw assembly having a ball joint with an improved locking force.

A pedicle screw assembly according to the present invention comprises a screw having a head with a convex portion and a receiver receiving the head. The receiver also receives an elongate member, such as a spinal fixation rod. (See the Specification from page 3, line 14 to page 4, line 2 and FIG. 1.) The receiver has a concave portion which has a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby to create an interference fit between the convex portion of the head and

the concave portion of the receiver. (See the Specification at page 4, lines 9 to 16 and FIG. 3.)

Preferably, a nut on the receiver compresses the convex portion of the head into the concave portion of the receiver. In one convenient orientation, the receiver comprises a U-shaped portion for receiving the elongated member. (See the Specification from page 3, line 27 to page 4, line 2 and FIG. 1) Preferably, the concave portion of the receiver is formed of titanium. (See the Specification at page 4, lines 18 to 32.) In one preferred orientation each of the concave portion and convex portion have a spherical shape. (See the Specification at page 2, lines 9 to 11 and FIGS. 1 and 2.)

In one preferred embodiment the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof and the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture. The receiver further comprises a channel therethrough opposite the aperture, the channel receiving the elongate member. (See the Specification from page 3, line 14 to page 4, line 2 and FIG. 1.)

The pedicle screw can further comprises a compression member between the elongate member and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an interference fit between the head and the pressure member. (See the Specification at page 2, lines 23 to 30 and from page 3, line 27 to page 4, line 2.)

The difference in the radius of curvature between the convex and concave portions in one embodiment is about 0.05 mm. (See the Specification at page 2, lines 32 to 34.)

VI. ISSUES FOR APPEAL

- A. Whether the Examiner properly rejected claims 1 to 3, 5 and 6 under 35 U.S.C. § 102(b) over the Tatar U.S. Patent No. 5,910,142?
- B. Whether the Examiner properly rejected claims 1 to 3 and 5 to 7 under 35 U.S.C. § 102(b) over the Biedermann et al. U.S. Patent No. 5,443,467?
- C. Whether the Examiner properly rejected claim 4 under 35 U.S.C. § 103(a) over Tatar in view of the Sherman et al. U.S. Patent No. 5,885,286?
- D. Whether the Examiner properly rejected claim 8 under 35 U.S.C. § 103(a) over Biedermann et al.?

VII. GROUPING OF THE CLAIMS

For purposes of this appeal only, the claims stand and fall together as per their grouping in the individual rejections.

VIII. ARGUMENT

Each of the rejections seems to stem from a misinterpretation of the term “interference fit”. Applicant defined the term in the specification on page 4, lines 6 to 14, “[t]he concave surface 26 has a slightly smaller radius of curvature than does the convex surface 18 so that when the two are compressed together, the material deforms somewhat to allow the surfaces to mate in an interference fit and thus enhances the grip between the surfaces.” Further, Applicant provided the Examiner with the definition of the term from Webster’s New International Dictionary, Second Edition Unabridged, which describes an interference fit as “one in which there is an interference of metal between the shaft and hole, even when the hole is the largest and the shaft the smallest that the specified tolerances permit”. A copy of this definition is attached. Applicant submits that the

Examiner has improperly extended the definition beyond its meaning as defined in the Specification and beyond its commonly accepted meaning.

Additionally, the Examiner appears to have ignored the limitation of claim 1 that the radius of curvature of the concave portion is less than the radius of curvature of the convex portion. The Examiner points out how the references define that the parts have radii of curvature, but fails to point out where in the references they state that the radius of the concave part is less than the radius of the convex part. The Examiner's misapplication of the concept of an interference fit and her disregard of the limitation of differing radii pervade each of the specific rejections discussed below.

The Examiner has improperly rejected claims 1 to 3, 5 and 6 under 35 U.S.C. § 102(b) over the Tatar U.S. Patent No. 5,910,142. Tatar discloses a pedicle screw device with a curvate head received by a cylindrical body element. The *“head 104 includes a constant radius of curvature lower portion 106 which is convex and therefore defines a partial hemispherical section.”* (column 5, line 5-7). *“The body element includes a curvate taper 126 which forms a socket, preferably having the identical radius of curvature of the lower half 106 of the screw 100.”* (column 5, line 24-27 - emphasis added). Tatar makes no express or implied indication of an interference fit between the screw and the body element. Rather than a smaller radius on the convex part it teaches identical radii.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a prior art reference. Tatar expressly fails to incorporate an interference fit in its device. Rather, Tatar specifically discloses an identical radius of curvature between the screw and body. Identical does not mean “less than.”

The Examiner improperly rejected claims 1 to 3 and 5 to 7 under 35 U.S.C. § 102(b) over the Biedermann et al. U.S. Patent No. 5,443,467. Biedermann et al. show a

bone screw with a spherical screw head and a cylindrical receiver member. Further “*the radius of the spherical surface corresponds substantially to the radius of the spherical segment-shaped portion of the head.*” (column 2, lines 53-54).

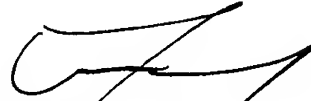
Biedermann et al. do not expressly disclose a device with an interference fit. Rather, they propose “substantial correspondence” between the radius of curvature of the screw and the receiver. “Substantial correspondence” demonstrates intent to achieve identical radii of curvature. This language fails to imply the use of an interference fit, which utilizes intentionally non-identical radii. Biedermann et al. introduce no language that suggests that an interference fit could improve the device. As with Tatar, Biedermann et al. not only fails to teach the invention, this reference teaches away from the present invention. As Biedermann et al. fail to teach an interference fit and fail to teach the radius of curvature of the concave part being less than the radius of curvature of the convex part Biedermann et al. can not anticipate and the rejection must fail.

The Examiner improperly rejected claim 4 under 35 U.S.C. § 103(a) over Tatar in view of Sherman et al. Sherman adds nothing regarding the concept of an interference fit. The Tatar device contains express intent to avoid non-identical radii, fundamental to an interference fit, and thus teaches away from the present invention. As both Sherman et al. and Tatar fail to teach or suggest this concept, the rejection must fail.

The Examiner improperly rejected claim 8 under 35 U.S.C. § 103(a) over Biedermann et al. The Examiner stated that it would have been within the skill in the art to provide a pedicle screw having a radius of curvature of 0.05 mm. However, claim 8 does not define a radius of curvature of 0.05 mm, but rather defines a difference in the radius of curvature between the convex and concave surfaces of 0.05mm. Neither the limitation that the radii are different, nor the claimed magnitude of the difference are taught or suggested by Biedermann. Biedermann sought substantially identical radii.

Applicant submits that each of the rejections were improper for the
aforementioned reasons. Accordingly, Applicants request that the Board to reverse the
Examiner's rejection and order allowance of the present claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Andrew C. Farmer', written over a horizontal line.

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March 18, 2004

Appendix

The Claims on Appeal

1. A pedicle screw assembly comprising:
a screw having a head with a convex portion;
a receiver receiving the head and an elongated member; and
the receiver having a concave portion, the concave portion having a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby to create an interference fit between the convex portion of the head and the concave portion of the receiver.
2. A pedicle screw assembly according to claim 1 and further comprising a nut on the receiver which compresses the convex portion of the head into the concave portion of the receiver.
3. A pedicle screw assembly according to claim 2 wherein the receiver comprises a U-shaped portion for receiving the elongated member.
4. A pedicle screw assembly according to claim 2 wherein the concave portion of the receiver is formed of titanium.
5. A pedicle screw assembly according to claim 1 wherein each of the concave portion and convex portion have a spherical shape.
6. A pedicle screw assembly according to claim 1 wherein the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof;
wherein the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture;

wherein the receiver further comprises a channel therethrough opposite the aperture, the channel receiving the elongate member.

7. A pedicle screw according to claim 6 and further comprising a compression member between the elongate member and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an interference fit between the head and the compression member.

8. A pedicle screw according to claim 1 wherein the radius of curvature of the concave portion is about 0.05 mm smaller than the radius of curvature of the convex portion.

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Med. & Veter. An abnormal passage leading from an abscess or hollow organ to the surface, or from one hollow organ to another; as, a salivary *fistula*.
Veter. A deep-seated, very resistant, suppurative inflammation of the subcutaneous and intermuscular connective tissues of the region of the withers of the horse.

tu-la (fist'ul-ā), *n.* [NL., fr. *L. fistula* a pipe, tube.] **Zool.** A genus of burrowing bivalve mollusks of the family Gastrochilidae.

tu-lar (fist'ul-ār), *adj.* [*L. fistularis*.] **Fistulous;** fistuliform.

tu-lar-i-a (-lār'ī-ā), *n.* [*NL., fr. L. fistula* pipe.] **Zool.** A genus of hemichordates, the type of a small family, *Fistularia* (-lār'ī-ā), *n.* [*L. fistularia*].

Fistularia (*F. labacaria*). West Indies.

Structurally closely related to the sticklebacks, having the head prolonged into a tube, with the mouth at the extremity. The species inhabit warm seas and are among those termed *Aulemouthis*.

tu-lar-i-oid (-lār'ī-ōid; 79), *adj. & n.* [*fistula* + *-i-oid*.] **Surg.** An instrument used in operations for fistula.

tu-lar-i-ous (-lār'ī-ōs), *adj.* **Fistulous.** **Rare.**

tu-lar-i-um (-lār'ī-ūm), *n.* [*F.*] A fistula.

tu-lar-i-um (-lār'ī-ūm), *adj.* [*fistula* + *-um*.] (Of a fistular form; tubular; pipe-shaped.)

tu-lar-i-na (-lār'ī-nā), *n.* [*NL., fr. L. fistula* pipe, tube.] **Bot.** A genus of fungi allied to *Boletus*, but having each of the tubes distinct. *F. hepatica* is the beefsteak fungus.

tu-lar-i-za (-lār'ī-zā), *v. t.* **Med.** To produce a fistula in or from; as, to *fistularize* the bladder.

tu-lar-i-za (-lār'ī-zā), *adj.* [*L. fistularis*.] **Fistulous.**

tu-lar-i-za (-lār'ī-zā), *adj.* **Med. & Veter.** Having the form or nature of a fistula; pertaining to, or having, a fistula; as, a *fistularious ulcer*; *fistularious withers*.

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2. Process of fitting; a making fit; preparation, as for higher study; as, a *fit* for college. *Colloq.*

3. One, esp. a garment, that fits.

4. *Mach.* Coincidence of parts in contact; tightness of adjustment of adjacent parts. A *running fit* is one used for parts that turn on one another; a *sliding fit* for parts that slide on one another. A *clearance fit* is one in which there is clearance between the shaft and hole even when the shaft is the largest and the hole the smallest that the specified tolerances permit. An *interference fit* is one in which there is an interference of metal between the shaft and hole, even when the hole is the largest and the shaft the smallest that the specified tolerances permit. A *transition fit* is one in which either a clearance or interference fit may be obtained within the limits of tolerance specified. The American Standards Association recognizes the following eight classes of fits: (1) a *loose fit*, with a recommended allowance between the parts of 0.0025 \sqrt{D} (D being the diameter); (2) a *free fit*, with a recommended allowance of 0.0014 \sqrt{D} , suitable for journals and bearings having speeds of 600 revolutions per minute or over, and a journal pressure of 800 pounds per square inch or over; (3) a *medium fit*, with a recommended allowance of 0.0009 \sqrt{D} , suitable for a sliding fit or for a running fit in which speed and pressure are less than the amounts specified above; (4) a *snug fit*, with no allowance, the closest fit that can be assembled by hand, for parts that are not to move against each other; (5) a *wrapping or tunking fit*, having an average metal interference of zero, obtained by selective assembly; (6) a *tight fit*, having an average interference of 0.0025 \sqrt{D} and requiring light pressure in assembling; (7) a *force fit*, either a *medium force fit*, having an average interference of 0.0005 \sqrt{D} , requiring considerable pressure in assembling; or (8) a *heavy force fit*, or *shrink fit*, having an average interference of 0.0001 \sqrt{D} .

5. *Math.* See CURVE FITTING.

6. *Soap Mfg.* See 4th FIT, 10.

fit (fīt), *n.* [*AS, strife, fight, of uncert. origin.*] 1. A painful, dangerous, exciting, or mortal crisis or experience. *Obs.*

2. A sudden and violent attack of a disorder; a stroke of disease, esp. epilepsy or apoplexy, which produces convulsions or unconsciousness; a convulsion; a paroxysm; hence, a period of exacerbation of a disease or physical disturbance, as, a *fit* of sickness; a *fit* of coughing.

3. A mood, passing humor, or caprice of any kind; a temporary absorbing affection; an outburst; as, a *fit* of laughter, of jealousy; esp., an outburst of anger.

4. A sudden and transitory motion, or spell of activity or inactivity; an impulsive and irregular action; as, a *fit* of industry; a *fit* of laziness.

5. A brief period; a spell. "A *fit* of good weather." *Swiss.*

Syn. — Attack; stroke; outbreak; whim, fancy.

— *v. t.* To force by paroxysms. *Obs.*

— *by fits, by fits and starts.* By intervals of action and repose; impulsively and irregularly; intermittently.

fit as a fiddle. Highly fit (sense 6); in trim.

fit (fitch), *n.* [*See FITCH.*] 1. Var. of *FITCH*. *Now Dial.*

2. *pl.* A word in the Authorized Version of the Bible, representing different Hebrew originals. In Isaiah xviii. 25, 27, it means the black aromatic seeds of *Nigella arvensis*. In Ezekiel iv. 9, the Revised Version reads *spelt*.

fit, *n.* [*See FITCH.*] 1. The fitch; its fur or pelt.

2. A small brush made of the hair of a fitch, skunk, or hog.

fit, *v. i.* [*See FITCH.*] To fitch. *Obs. & N. of Eng.*

fitch (fitch), *adj.* *Her. Fitchée.*

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